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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,725	01/21/2000	Yuanhua T. Tang	784	4830

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/488,725	TANG ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to a collection of polypeptides comprising at least one of a recited list of SEQ ID NO's, classified in class 536, subclass 24.3. This Group is also subject to election of species requirements, set forth below.

II. Claims 9-10, directed to a computer readable medium comprising sequence information, classified in class 702, subclass 20. This Group is also subject to election of species requirements, set forth below.

III. Claims 11-12, and 17-18, directed to a polynucleotide, a vector and host cell comprising the polynucleotide, and an antisense polynucleotide, classified in class 536, subclass 23.1. This Group is also subject to a restriction to a single SEQ ID NO, as set forth below.

IV. Claims 13-15 and 19, directed to a polypeptide and a composition comprising the polypeptide, classified in class 530, subclass 350. This Group is also subject to a restriction to a single SEQ ID NO, as set forth below.

V. Claim 16, directed to an antibody, classified in class 530, subclass 387.1. This Group is also subject to a restriction to a single SEQ ID NO, as set forth below.

The inventions are distinct, each from the other because of the following reasons:

Invention II is not related to any of Inventions I and III-V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions I and III-V are directed to biochemical structures comprising nucleotides or amino acids, whereas Invention II is directed to a device. Structures comprising

nucleotides and amino acids have biochemical and physical properties quite different than those of a computer-readable medium, and would be expected to behave differently in methods of use. Thus, while the information stored on the device of Group II may have some relationship to the structures of other Groups, the device of Group II is nonetheless not capable of use with the biochemical entities of Groups I and III-V, has a different mode of operation, a different function and would be expected to have different effects than the products of Groups I and III-V.

Groups I and III are separate and distinct. While the Groups are related in that the collection of Group I may comprise the individual polynucleotide of Group III, a collection of polynucleotides would necessarily have different properties than would a single polynucleotide, and would be expected to behave differently in methods of use and produce different results. For these reasons, Group I is separate and distinct from Group III.

Groups I and III are separate and distinct from Group IV because the inventions are directed to different chemical types regarding the critical limitations therein. For Group IV, the critical feature is a polypeptide whereas for Groups I and III the critical feature is a polynucleotide or collection thereof. It is acknowledged that various processing steps may cause a polypeptide of Group IV to be directed as to its synthesis by a polynucleotide of Group III, however, the completely separate chemical types of the inventions of Groups III and IV supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if searched together, as compared to being searched separately. Also, it is pointed out that although processing may connect two groups, such a connection does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Each of Inventions I and III is separate and distinct from Group V, as the claims of Inventions I and III are drawn to polynucleotides, while the claim of Group V is drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention V would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

Inventions IV is separate and distinct from Invention V as the polypeptides of Invention IV is structurally and biochemically different than the antibody of Invention V. While the antibody of Group V may bind to the polypeptide of Group IV, the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner. Invention IV is therefore separate and distinct from Invention V.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Further, because these inventions are distinct for the reasons given above and the search required for Group I is not required for any other Group, restriction for examination purposes as indicated is proper.

Election of Species Requirement for Groups I and II

This application contains claims directed to the following patentably distinct species of the claimed invention. If Group I or II is elected, then applicant is required to elect one of the following species (a) a collection comprising at least one full-length polypeptide selected from SEQ ID NO's 1-10,289; (b) a collection comprising at least a segment of any one of SEQ ID NO's 1-10,289.

If either of Groups I or II is elected, then applicant is further required to elected a single SEQ ID NO: for purposes of facilitating search and examination. Applicant is reminded that election of a single SEQ ID NO: is considered a species requirement ONLY for Groups I and II.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Sequence Election Requirement Applicable to Groups III-V

In addition, Groups III-V detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated

sequences and each unrelated sequence is considered a separate and distinct product, therefore a further restriction is applied to each Group. For an elected Group drawn to either amino acid or polypeptide sequences, the applicant must further elect a **single** amino acid or a **single** polypeptide sequence. (See MPEP 803.04). Due to the increasingly large size of sequence databases which must be searched and the increasing numbers of applications requiring sequence searches, it creates an undue burden on the Office to search more than a single sequence (product) per application. For these reasons, the requirements of 37 CFR 1.141 et seq. are no longer waived and applicant is required to elect a single sequence for examination. Applicant is reminded that, for Groups III-V, this is a **restriction requirement**, not an election of species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention and the SEQ ID number to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

mam

Marjorie A. Moran
6/2/04